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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,061	06/01/2005	Ira Pastan	4239-67287-05	2145
36218 7590 08/14/2007 KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE #1600 PORTLAND, OR 97204-2988			EXAMINER BLANCHARD, DAVID J	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 08/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,061	<b>Applicant(s)</b> PASTAN ET AL.	
	<b>Examiner</b> David J. Blanchard	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6,8,10-13 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8,10-13 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 5, 7, 9, 14-20 and 34-38 are cancelled.  
Claims 6, 10 and 13 have been amended.
2. Claims 24-38 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. Claims 1-4, 6, 8, 10-13 and 21-23 are under consideration.

### ***Objections/Rejections Withdrawn***

4. The objection to the abstract as not commencing on a separate sheet accordance with 37 CFR 1.52(b)(4) is withdrawn in view of the newly submitted abstract filed 5/21/2007.
5. The objection to the specification as containing embedded hyperlinks and/or other form of browser-executable code is withdrawn in view of the amendments to the specification filed 5/21/2007.
6. The objection to the specification as disclosing "??ORIGINALLY" is withdrawn in view of the amendments to the specification filed 5/21/2007.
7. The objection to claim 10 as depending from a cancelled claim is withdrawn in view of the amendment to the claim.
8. The rejection of claims 6-8 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "heavy chain framework region comprising a complementarity determining region..." in claim 6 is withdrawn in view of the amendments to the claims.
9. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "light chain framework region comprising a complementarity determining region..." is withdrawn in view of the cancellation of the claim.
10. The rejection of claim 7 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the cancellation of the claim.

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11. The rejection of claim 7 under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims is withdrawn in view of the cancellation of the claim.

12. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Modak et al (Cancer Research, 61:4048-4054, May 15 2001, Ids reference filed 6/1/05) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is withdrawn in view of the cancellation of the claim.

13. The rejection of claim 7 under 35 U.S.C. 103(a) as being obvious over Cheung [a] (US 2002/0102264 A1, filed 10/18/2001) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is withdrawn in view of the cancellation of the claim.

14. The rejection of claim 7 under 35 U.S.C. 103(a) as being obvious over Cheung [b] (US 2003/0103963 A1, priority to at least 10/18/2001) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is withdrawn in view of the cancellation of the claim.

15. The rejection of claim 7 under 35 U.S.C. 103(a) as being obvious over Cheung [c] (US 2005/0169932 A1, priority to at least 10/18/2001) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is withdrawn in view of the cancellation of the claim.

16. The provisional rejection of claim 7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-7, 9, 11 and 52-54 of copending Application No. 10/097,558 in view of Reiter et al (Biochemistry, 33:5451-5459, 1994) is withdrawn in view of the cancellation of the claim.

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17. The provisional rejection of claims 1-3, 6-8, 10-13 and 21-23 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-5 and 11-23 of copending Application No. 10/505,658 in view of Reiter et al (Biochemistry, 33:5451-5459, 1994) is withdrawn in view of the cancellation of the claims 2-5 and 11-23 in copending Application No. 10/505,658. It is noted that claim 7 of the present application has been canceled.

### ***Rejections Maintained***

#### ***Claim Rejections - 35 USC § 112***

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. The rejection of claims 1-4, 6, 8, 10-13 and 21-23 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is maintained.

The response filed 5/21/2007 states that example 2 of the present specification indicates that the DNA encoding the VL and the VH-PE38 protein were deposited with the ATCC as accession numbers PTA-5661 and PTA-5660. Applicant encloses a deposit receipt from the ATCC and a copy of Form PCT/RO/134 that was published with the parent PCT application and states that this form acknowledges that the International Bureau has reviewed the deposit information for PTA-5661 and PTA-5660. Applicants' arguments and enclosures have been fully considered but are not found persuasive. While the DNA encoding the VH and VL regions of monoclonal antibody 8H9 have been

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deposited, the claims require that the Fv protein specifically bind the epitope bound by monoclonal antibody 8H9. Thus, monoclonal antibody 8H9 is required to practice the claimed invention, and monoclonal antibody 8H9 also comprises a constant light chain region, and the heavy chain comprises a CH1 domain, hinge, CH2 and CH3 regions in addition to the VH and VL regions. Thus, because the VH and VL regions do not convey the complete structure of monoclonal antibody 8H9, and monoclonal antibody 8H9 is required to practice the claimed invention, the rejection is maintained.

20. The rejection of claims 6, 8 and 10-12 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated Fv protein comprising a heavy chain variable region comprising the HCDR1 of residues 31-35 of SEQ ID NO:3, the HCDR2 of residues 50-60 of SEQ ID NO:3 and the HCDR3 of residues 99-107 of SEQ ID NO:3 and a light chain variable region comprising the LCDR1 of residues 157-167 of SEQ ID NO:3, the LCDR2 of residues 183-189 of SEQ ID NO:3 and the LCDR3 of residues 222-230 of SEQ ID NO:3 wherein the Fv protein binds the 8H9 antigen, does not reasonably provide enablement for an isolated Fv protein comprising a heavy chain variable region comprising a complementarity determining region (CDR) that comprises an amino acid sequence of residues 31-35, 50-65 or 99-107 of SEQ ID NO:3 and/or comprising a light chain variable region comprising a CDR that comprises an amino acid sequence of residues 157-167, 183-189 or 222-230 of SEQ ID NO:3 wherein the Fv protein does not bind the 8H9 antigen as broadly encompassed by the claims is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The response filed 5/21/2007 states that in the interest of advancing prosecution, claim 6 has been amended to clarify that the claimed antibodies include three H-CDRs and three L-CDRs. Applicants' arguments have been fully considered but are not found persuasive. Claim 6 as presently amended does not include all six CDRs of SEQ ID NO:3 because as noted in the previous Office Action the phrase "comprises an amino acid sequence" reads upon fragments of the recited CDR sequences, since a fragment

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comprising two amino acids of amino acids 99-107 of SEQ ID NO:3, for example, is merely one interpretation of "an amino acid sequence" of residues 99-107 of SEQ ID NO:3. Thus, the claims still broadly encompass isolated Fv proteins that do not contain all six CDRs of monoclonal antibody 8H9, three from the heavy chain variable domain and three from the light chain variable domain and do not bind the 8H9 antigen and the rejection is maintained for reasons of record. Amending the claims to recite "comprises the amino acid sequence..." would overcome this rejection.

### ***Claim Rejections - 35 USC § 103***

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. The rejection of claims 1-3, 6, 8, 10-12 and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Modak et al (Cancer Research, 61:4048-4054, May 15 2001, Ids reference filed 6/1/05) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is maintained.

23. The rejection of claims 1-3, 6, 8, 10-12 and 21-23 under 35 U.S.C. 103(a) as being obvious over Cheung [a] (US 2002/0102264 A1, filed 10/18/2001) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is maintained.

24. The rejection of claims 1-3, 6, 8, 10-12 and 21-23 under 35 U.S.C. 103(a) as being obvious over Cheung [b] (US 2003/0103963 A1, priority to at least 10/18/2001) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is maintained.

25. The rejection of claims 1-3, 6, 8, 10-12 and 21-23 under 35 U.S.C. 103(a) as being obvious over Cheung [c] (US 2005/0169932 A1, priority to at least 10/18/2001) in view of Robinson et al (U.S. Patent 5,618,920, issued 4/8/1997, cited on PTO-892 mailed 10/13/06) and Reiter et al (Biochemistry, 33:5451-5459, 1994) and Queen et al (US Patent 5,530,101, issued 6/25/1996) is maintained.

The response filed 5/21/2007 addresses the above rejections by submitting a Declaration of Dr. Pastan under 37 C.F.R. 1.132, which documents the unexpectedly superior properties of the 8H9 dsFv linked to a toxin (PE38) as compared to the 8H9 scFv linked to PE38. The declaration documents the unexpected finding that the 8H9 dsFv showed substantially less toxicity than the scFv form, which according to applicant could not have been predicted based on the teachings of Modak et al, Cheung [a], Cheung [b] and Cheung [c]. The declaration documents that the yield of 8H9 dsFv-PE38 is unexpectedly superior when compared to the yield of 8H9 scFv-PE38 and the



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toxicity of 8H9 dsFv-PE38 was surprisingly less than the toxicity of the 8H9 scFv-PE38. Applicants' arguments and the Declaration of Dr. Pastan under 37 C.F.R. 1.132 have been carefully considered but are not found persuasive. The examiner agrees that the unexpected findings of the 8H9 dsFv compared to the 8H9 scFv with which applicant argues could not be predicted based on the primary references of each of the above rejections, i.e., Modak et al, Cheung [a], Cheung [b] and Cheung [c], however, applicant is reminded that the present rejections are based on the combined teachings of the cited references and what their teachings would have reasonably suggested to one of ordinary skill in the art at the time the invention was made. Reiter et al teaches that dsFv-immunotoxins are obtained in increased yields due to a decreased tendency of properly folded dsFv-immunotoxins to aggregate and dsFv-immunotoxins are easier to produce with high yields and are more stable than scFv-immunotoxins and dsFv-immunotoxins (and dsFvs alone) might be more useful than scFv's in clinical and other applications that require large amounts of stable recombinant Fv's (see pg. 5455, 5458 and abstract). Thus, applicants' claimed 8H9 dsFv-PE38 is *prima facie* obvious to one of ordinary skill in the art because the evidence submitted does not prove any results beyond what one of ordinary skill in the art might have expected based on the teachings of the references, which indicates that dsFv-immunotoxins are easier to produce with high yields and are more stable than scFv-immunotoxins. The evidence submitted does not prove any results beyond what one of ordinary skill in the art might have expected adequate to rebut the *prima facie* case of obviousness. *Ex parte The Nutrasweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967) See MPEP 716.02(c).

Applicants' arguments and evidence that the toxicity of 8H9 dsFv-PE38 is substantially less than the toxicity of 8H9 scFv-PE38 is acknowledged, however, applicant has not explained the statistical significance or practicality of the "unexpected finding" and how it supports a conclusion of nonobviousness. The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious

and of both statistical and practical significance." *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Further, the other evidence provided in the declaration and in the specification at pg. 47 (Table 1) demonstrates that 8H9 dsFv-PE38 showed cytotoxic and antitumor activities similar to those of 8H9 scFv-PE38, was well tolerated in monkeys and a dose that causes significant tumor regression in mice is well tolerated by monkeys. Consistent with the similar cytotoxic and antitumor activities between the 8H9 dsFv and scFv immunotoxins, Reiter teaches that dsFv-immunotoxins have equal or better cytotoxic activities than scFv-immunotoxins. Additionally, the submission of evidence that a new product possesses unexpected properties does not necessarily require a conclusion that the claimed invention is nonobvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979). In the instant case and as set forth in the previous Office Action, one of ordinary skill in the art at the time the invention was made would have been motivated and had a reasonable expectation of success to produce humanized 8H9 dsFv-immunotoxins that are less immunogenic in human tumor patients, are easier to produce in high yields and are more stable than scFv-immunotoxins (e.g., see Reiter et al). Thus, one of ordinary skill in the art at the time the invention was made would have been motivated by the art recognized advantages of reducing immunogenicity in human cancer patients, increased stability and higher yields of dsFv-immunotoxins compared to scFv-immunotoxins and equal or better cytotoxicity of dsFv-immunotoxins compared to scFv-immunotoxins, to produce humanized 8H9 dsFv-immunotoxins for therapeutic benefit in human cancer patients. "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). See MPEP 2145.

For these reasons and those already of record, the above obviousness rejections under 35 U.S.C. 103(a) are maintained.

### ***Double Patenting***

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. The provisional rejection of claims 1-3, 6, 8, 10-13 and 21-23 are on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-7, 9, 11 and 52-54 of copending Application No. 10/097,558 in view of Reiter et al (Biochemistry, 33:5451-5459, 1994) is maintained.

The response refers to the Declaration of Dr. Pastan as documenting the non-obviousness of the presently claimed invention and applicant requests that this rejection be held in abeyance until allowable subject matter is identified. Applicants' arguments and the Declaration of Dr. Pastan have been fully considered but are not found persuasive in view of the examiners above remarks regarding the obviousness rejection. Further, in view that no terminal disclaimer has been filed, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common

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ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/097,558, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

28. Claims 1-3, 6, 8, 10-13 and 21-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-10 of copending Application No. 10/505,658 in view of Reiter et al (Biochemistry, 33:5451-5459, 1994) is maintained.

The response refers to the Declaration of Dr. Pastan as documenting the non-obviousness of the presently claimed invention and applicant requests that this rejection be held in abeyance until allowable subject matter is identified. Applicants' arguments and the Declaration of Dr. Pastan have been fully considered but are not found persuasive in view of the examiners above remarks regarding the obviousness rejection. Further, in view that no terminal disclaimer has been filed, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/505,658, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35

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U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

29. No claims are allowed.

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/  
Primary Examiner, A.U. 1643